

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>4239-68226-01</b>	<b>FOR FURTHER ACTION</b> see Form PCT/ISA/220 as well as, where applicable, Item 5 below.	
International application No. <b>PCT/US2004/017736</b>	International filing date (day/month/year) <b>04/06/2004</b>	(Earliest) Priority Date (day/month/year) <b>05/06/2003</b>
Applicant  <b>THE GOVERNMENT OF THE UNITED STATES OF AMERICA...</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**POLY-GAMMA-GLUTAMIC ACID CONJUGATES FOR ELICITING IMMUNE RESPONSES DIRECTED AGAINST BACILLI**

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☒ none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2004/017736

**Box No. I** Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☒ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing
    - ☒ contained in the international application as filed
    - ☐ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purpose of search
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

PCT/US04/17736

IAP8 Rec'd PCT/PTO 02 DEC 2005

51

## ABSTRACT

Immunogenic compositions and methods for eliciting an immune response against *B. anthracis* and other bacilli are provided that include immunogenic conjugates of a poly- $\gamma$ -glutamic acid ( $\gamma$ PGA) polypeptides of *B. anthracis*, or of another *Bacillus* that expresses a  $\gamma$ PGA polypeptide. 5 The  $\gamma$ PGA conjugates elicit an effective immune response against *B. anthracis*, or against another *Bacillus*, in mammalian hosts to which the conjugates are administered.

< The preferred conjugate consists of  $\gamma$ -D-PGA and *Bacillus* protective antigen. >

BEST AVAILABLE COPY

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/017736

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07K14/32 A61K39/07 A61P31/04 C07K16/12

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ALKAN, SEFIK S. ET AL: "Antigen recognition and the immune response. Capacity of L-tyrosine-azobenzenearsonate to serve as a carrier for a macromolecular hapten" JOURNAL OF IMMUNOLOGY, 107(2), 353-8 CODEN: JOIMA3; ISSN: 0022-1767, 1971, XP009039727	1-5, 7-9, 11-33
Y	abstract; page 354, right-hand column, second paragraph; paragraph joining pages 355 and 356; page 356, paragraph joining left- and right-hand column; page 357, left-hand column, first paragraph ----- -/--	6, 10



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*8\* document member of the same patent family

Date of the actual completion of the international search

18 November 2004

Date of mailing of the international search report

08/12/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Fausti, S

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GOODMAN J W ET AL: "Immunochemical studies on the poly-gamma-D-glutamyl capsule of Bacillus anthracis. 3. The activity with rabbit antisera of peptides derived from the homologous polypeptide." BIOCHEMISTRY. FEB 1968, vol. 7, no. 2, February 1968 (1968-02), pages 706-710, XP001203672 ISSN: 0006-2960 abstract; page 706; right-hand column, lines 10-13	28-31
X	----- DATABASE MEDLINE 'Online! US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; February 1975 (1975-02), KLAUS G G ET AL: "The immunological properties of haptens coupled to thymus-independent carrier molecules. III. The role of the immunogenicity and mitogenicity of the carrier in the induction of primary IgM anti-hapten responses." XP002306078 Database accession no. NLM10166 abstract & EUROPEAN JOURNAL OF IMMUNOLOGY. FEB 1975, vol. 5, no. 2, February 1975 (1975-02), pages 105-111, ISSN: 0014-2980	1-4,7-9, 11-19, 32,33
X	----- SENYK, GEORGE ET AL: "Immune response to glucagon in conjugated form" IMMUNOCHEMISTRY, 9(2), 97-110 CODEN: IMCHAZ; ISSN: 0019-2791, 1972, XP009039720 abstract; paragraph joining pages 98 and 99	1-4,7-9, 11-19, 32,33
X	----- F PRODHOMME EMMANUEL J -P ET AL: "Poly-gamma-D-glutamic acid as a template for functionalized water-soluble biomaterials" ABSTRACTS OF PAPERS AMERICAN CHEMICAL SOCIETY, vol. 219, no. 1-2, 2000, page BIOL 133, XP009039728 & 219TH MEETING OF THE AMERICAN CHEMICAL SOCIETY.; SAN FRANCISCO, CALIFORNIA, USA; MARCH 26-30, 2000 ISSN: 0065-7727 abstract	1-4,7,8, 11-17
	----- -/--	

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	SCHNEERSON RACHEL ET AL: "Poly(gamma-D-glutamic acid) protein conjugates induce IgG antibodies in mice to the capsule of Bacillus anthracis: A potential addition to the anthrax vaccine." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA, vol. 100, no. 15, 22 July 2003 (2003-07-22), pages 8945-8950, XP002306072 ISSN: 0027-8424 the whole document	1-33
Y	LEPPLA STEPHEN H ET AL: "Development of an improved vaccine for anthrax" JOURNAL OF CLINICAL INVESTIGATION, vol. 110, no. 2, July 2002 (2002-07), pages 141-144, XP002306073 ISSN: 0021-9738 page 143, left-hand column, line 1 - right-hand column, line 11	6,10
A	WELKOS SUSAN ET AL: "The role of antibodies to Bacillus anthracis and anthrax toxin components in inhibiting the early stages of infection by anthrax spores" MICROBIOLOGY (READING), vol. 147, no. 6, June 2001 (2001-06), pages 1677-1685, XP002306074 ISSN: 1350-0872 abstract; page 1678, left-hand column, lines 7-14; paragraph joining pages 1682 and 1683; page 1684; paragraph joining left- and right-hand columns	1-33
A	WO 01/60412 A (GENZYME CORP) 23 August 2001 (2001-08-23) paragraph joining pages 6 and 7; claims 1 and 7	12-14

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2004/017736

## Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
Although claims 20-27 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/017736

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0160412	A	23-08-2001	AU 3834601 A	27-08-2001
			CA 2400205 A1	23-08-2001
			EP 1263472 A2	11-12-2002
			JP 2003522806 T	29-07-2003
			WO 0160412 A2	23-08-2001
			US 2003087877 A1	08-05-2003
			US 2004209842 A1	21-10-2004
<hr/>				